

EPA Registration No.
82012-3 vol. 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 27 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Joseph J. Green
Counsel to the Copper Development Association
Kelley Drye & Warren
Washington Harbour, Suite 400
3050 K Street, NW
Washington, D.C. 20007-5108

Subject: Antimicrobial Copper Alloys Group I
EPA Registration Number 82012-1
Antimicrobial Copper Alloys Group II
EPA Registration Number 82012-2
Antimicrobial Copper Alloys Group III
EPA Registration Number 82012-3
Antimicrobial Copper Alloys Group IV
EPA Registration Number 82012-4
Antimicrobial Copper Alloys Group V
EPA Registration Number 82012-5
Antimicrobial Copper Alloys Group VI
EPA Registration Number 82012-6
Your Submission(s) Dated April 24, 2013
EPA Received Dated April 29, 2013

Dear Mr. Green:

The Agency has completed the technical screen review of your application pursuant to Section 33(f)(4)(B)(i)(ii) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA), as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the technical screen and therefore is subject to rejection if the application is not corrected.

Specifically for,

Efficacy:

The submitted Clinical trial of the use of Antimicrobial Copper Alloys in reducing the amount of bacteria on touch surfaces in hospital intensive care units and the effect on the number of hospital acquired infections, was reviewed by the efficacy review section and

the human subject study expert. Due to the uniqueness of the submitted Clinical trial study, an internal Agency meeting was set up to discuss the infection reduction and bio-burden control claims that appear on the proposed product labeling. As an outcome of the Agency's internal meeting centered around the labeling claims being supported by the submitted clinical trial study, it was determined that the proposed labeling claims including infection reduction and bio-burden control needs to be reviewed and approved by the Food and Drug Administration before they can be added to the currently EPA registered labeling for the Antimicrobial Copper Alloys products.

Upon a cursory review of the submitted Clinical trial study, it needs to be submitted to the Human Hazards Review Board. The clinical trial study needs to be presented and reviewed by the Human Hazards Review Board. The studies must be submitted 75 (seventy-five) days before the day of the meeting. Please refer to the regulations: 40 CFR part 26 subpart Q provides the standards that EPA uses to assess whether on the results of human research in EPA actions and 40 CFR part 26.1303 provides the details on what ethics information must be submitted along with a human study.

Since the Clinical trial study was conducted in actual patients' hospital rooms, it must be presented and reviewed by the Human Hazards Review Board. This review will determine if the study is suitable for the Agency to review while supporting the infection reduction claims and bio-burden claims. The Human Hazards Review Board only meets once or twice a year. This review must take place before the Antimicrobials Division can review the study to support the proposed infection reduction and bio-burden claims.

In order for the review of your product to continue, you will need to correct your submission(s) to address the item(s) listed above within 10 business days of the date you received this letter. If you cannot correct the application or do not respond within 10 business days, your application will be rejected.

If you have questions, please contact Karen M. Leavy at Leavy.Karen@epa.gov or (703)-308-6237.

Sincerely,

Dennis H. Edwards for

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

DECISION PKG. NO. 478065
SUBMISSION BAR CODE # 934418

SUBM. DUE DATE 9/16/13
REVIEWER AD

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 82012-3 PM 33 ACTION CODE A570

DESCRIPTOR _____ **FQPA** **NFQPA** _____

[] CHILD RESISTANT PACKAGING: [] REQUIRED [] NOT REQUIRED
REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL [] RESTRICTED USE

DATE ON APPLICATION 4/15/13 EPA RECEIVE DATE 4/24/13 PM RECEIVE DATE 4/29/13

METHOD OF SUPPORT FORMULATORS EXEMPTION
[] CITE-ALL [] SELECTIVE [] SUBMITTED [] NOT SUBMITTED
[] NOT SUBMITTED [] N/A [] N/A

REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX.				
RASSB TOX.				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER:				

STATUS _____

RESPONSE CODE 1350 RESPONSE DATE 9/16/13

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY	AD	EASSB	CTT		
EFFICACY	AD	EASSB	RET		

KELLEY DRYE & WARREN LLP

A LIMITED LIABILITY PARTNERSHIP

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3050 K STREET, NW

WASHINGTON, D.C. 20007-5108

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JOSEPH J. GREEN

DIRECT LINE: (202) 342-8849

EMAIL: jgreen@kelleydrye.com

July 3, 2013

Marshall Swindell
Project Manager 33
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C.
Swindell.Marshall@epa.gov

**Re: Withdrawal of Applications to Amend Registration for Antimicrobial
Copper Alloys Groups I-VI (EPA Reg. Nos. 82012-1 through -6) to
Include Claims Related to Results of Clinical Trials**

Dear Mr. Swindell:

On behalf of the Copper Development Association ("CDA"), and in response to your June 27, 2013 "technical review" letter, we hereby withdraw our applications (dated April 24, 2013) to amend the registrations for Antimicrobial Copper Alloys Groups I-VI. As discussed during our June 20th meeting, the withdrawal is based on our agreed understanding that the Antimicrobials Division will engage in consultations with the Food and Drug Administration ("FDA") – after CDA has met with FDA and organized such consultations – to review the clinical trial study submitted in support of the proposed labeling claims that were the subject of the amendment applications. As noted at our meeting, the Antimicrobials Division does not have the expertise or experience to review clinical trial studies and, accordingly, as the June 27th letter states, the proposed claims need to be reviewed and approved by FDA before they can be added to the existing EPA registered label for Antimicrobial Copper Alloys.

CDA representatives have made contact with the appropriate FDA officials and are in the process of arranging a meeting to discuss the clinical trial study. We will keep EPA informed of our progress with FDA. In the meantime, CDA has authorized, in a separate letter dated July 3, 2013, EPA to discuss and share information with FDA regarding the Antimicrobial Copper Alloy clinical trial study. Information on the FDA contact person for this matter is included in the authorization letter.

In addition, as discussed at our meeting and noted in your June 27th letter, CDA is arranging to have the clinical trial study approved by the Human Study Review Board at their upcoming meeting in October 2013. We have had initial contacts with Kelly Sherman and are preparing to submit to the HSRB by July 17th the requested study documentation.

We look forward to continuing our discussions regarding the label claims that are supported by the Antimicrobial Copper Alloy clinical trial study. We will keep EPA apprised of developments with FDA and the HSRB. If you have any questions or need anything else, please contact me at 202.342.8849 or JGreen@KelleyDrye.com.

Respectfully,



Joseph J. Green
Counsel to the Copper Development Association

cc: Susan Lewis, Director, Antimicrobials Division
Dennis Edwards, Branch Chief
John Hebert, Antimicrobials Division
Karen Leavy, Antimicrobials Division

DATA PACKAGE BEAN SHEET

Date: 22-May-2013

Page 1 of 2

Decision #: 478065

DP #: (411985)

PRIA

Parent DP #:

Submission #: 934418

E-Sub #:

*** Registration Information ***

Registration: 82012-3 - ANTIMICROBIAL COPPER ALLOYS - GROUP III

Company: 82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Karen Leavy KLEAVY

Sent Date: _____

PRIA Due Date: 16-Sep-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

Ingredients: 022501, Copper as elemental(82.6%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 22-May-2013

Due Back: _____

DP Ingredient: 022501, Copper as elemental

DP Title: _____

CSF Included: ☐ Yes ☒ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 17-Aug-2013

Team Name: EET

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Technical Screen review- CDA is submitted a clinical trial entitled Clinical Trial of the use of Antimicrobial Copper Alloys in Reducing the amount of Bacteria on Touch Surfaces in Hospital Intensive Care Units and the Effect on the Number of Hospital Acquired Infections, PRIA, Action Code A570, Technical Screen Due Date 7/1/13, PRIA due date 9/16/13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2137T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

Copper Development Association

260 Madison Avenue

New York, New York 10016 Tel: (202) 828-8967

EPA Registration Number/File Symbol

82012-3

Active Ingredient(s) and/or representative test compound(s)

Copper, metallic (PC Code 22501)

Date

April 11, 2013

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)

Indoor, Non-Food

Product Name

Antimicrobial Copper Alloys Group III

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Robert R. Stewart

Date

April 11, 2013

Typed or Printed Name and Title

Robert R. Stewart, Ph.D.
Regulatory Consultant



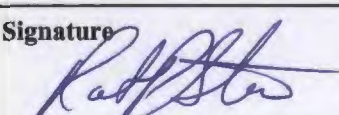
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved B No. 2070-0060

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DATA MATRIX

Date	April 11, 2013	EPA Reg. No./File Symbol	82012-3	Page 1 of 6	
Applicant's/Registrant's Name & Address:		Product			
Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016		Antimicrobial Copper Alloys Group III			
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY:					
830.1550	Product Identity and Composition	46999301 47259201	Copper Development Association	OWN	
830.1600	Description of Materials Used to Produce the Product	46999301	Copper Development Association	OWN	
830.1620	Description of Production Process	46999301	Copper Development Association	OWN	
830.1650	Description of Formulation Process	46999301	Copper Development Association	OWN	
830.1670	Discussion of Formation of Impurities	46999301	Copper Development Association	OWN	
830.1700	Preliminary Analysis	46999301 47160802	Copper Development Association	OWN	
830.1750	Certification of Limits	48899101	Copper Development Association	OWN	
830.1800	Enforcement Analytical Methods	46999301	Copper Development Association	OWN	
830.1900	Submittal of Samples	46999301	Copper Development Association		Upon Request
830.6302	Color	47160801	Copper Development Association	OWN	
830.6303	Physical State	47160801	Copper Development Association	OWN	
Signature		Name and Title		Date	
		Robert R. Stewart, Ph.D.		April 11, 2013	

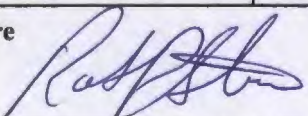


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Date April 11, 2013			EPA Reg. No./File Symbol 82012-3	Page 2 of 6	
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016			Product Antimicrobial Copper Alloys Group III		
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY (Cont.):					
830.6304	Odor	47160801	Copper Development Association	OWN	
830.6314	Oxidizing or Reducing Action	47160801	Copper Development Association	OWN	
830.6315	Flammability	47160801	Copper Development Association	OWN	
830.6316	Explosibility	47160801	Copper Development Association	OWN	
830.6317	Storage Stability	47160801	Copper Development Association	OWN	
830.6319	Miscibility	47160801	Copper Development Association	OWN	
830.6320	Corrosion Characteristics	47160801	Copper Development Association	OWN	
830.6321	Dielectric Breakdown Voltage	47160801	Copper Development Association	OWN	
830.7000	pH	47160801	Copper Development Association	OWN	
830.7100	Viscosity	47160801	Copper Development Association	OWN	
830.7300	Density, Bulk Density or Specific Gravity	47160801	Copper Development Association	OWN	
Signature 			Name and Title Robert R. Stewart, Ph.D.		Date April 11, 2013



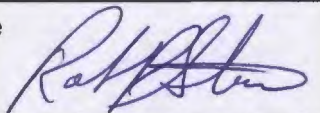
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DATA MATRIX

Date	April 11, 2013	EPA Reg. No./File Symbol	82012-3	Page 3 of 6	
Applicant's/Registrant's Name & Address:		Product			
Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016		Antimicrobial Copper Alloys Group III			
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY:					
870.1100	Acute Oral Toxicity: Rat	46999302	Copper Development Association	OWN	
870.1200	Acute Dermal Toxicity: Rat	46999302	Copper Development Association	OWN	
870.1300	Acute Inhalation Toxicity: Rat	46999302	Copper Development Association	OWN	
870.2400	Primary Eye Irritation: Rabbit	46999302	Copper Development Association	OWN	
870.2500	Primary Dermal Irritation	46999302	Copper Development Association	OWN	
870.2600	Dermal Sensitization	46999302	Copper Development Association	OWN	
870.3100	90-Day Oral Toxicity	46999302	Copper Development Association	OWN	
870.3150	90-Day Oral Toxicity -- Nonrodent	46999302	Copper Development Association	OWN	
870.3250	90-Day Dermal Toxicity	46999302	Copper Development Association	OWN	
870.3700	Teratology -- Rats	46999302	Copper Development Association	OWN	
870.3700	Teratology -- Rabbits	46999302	Copper Development Association	OWN	
Signature			Name and Title		Date
			Robert R. Stewart, Ph.D.		April 11, 2013

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.



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Date	April 11, 2013	EPA Reg. No./File Symbol	82012-3	Page 4 of 6	
Applicant's/Registrant's Name & Address:		Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016		Product Antimicrobial Copper Alloys Group III	
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY (Cont.):					
870.3800	Reproduction and Fertility Effects	46999302	Copper Development Association	OWN	
870.4100	Chronic Oral/Feeding Study	46999302	Copper Development Association	OWN	
870.5100	Bacterial Reverse Mutation (Ames) Test	46999302	Copper Development Association	OWN	
870 Genotoxicity Series	Other Mutagenicity	46999302	Copper Development Association	OWN	
870.7485	Metabolism and Pharmacokinetics - Rat	46999302	Copper Development Association	OWN	
Signature	Robert R. Stewart, Ph.D.		Name and Title		Date
			Robert R. Stewart, Ph.D.		April 11, 2013



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DATA MATRIX

Date	April 11, 2013	EPA Reg. No./File Symbol	82012-3	Page 5 of 6
Applicant's/Registrant's Name & Address:	Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016	Product	Antimicrobial Copper Alloys Group III	

Ingredient Copper as elemental (PC Code 22501)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY:					
810.2300	Hard Surface Sanitizer Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048)	46999306 46999310 46999312	Copper Development Association	OWN	
810.2300	Hard Surface Sanitizer Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442)	46999307	Copper Development Association	OWN	
810.2300	Hard Surface Sanitizer Assay: <i>VRE. Faecalis</i> (ATCC 51575)	47859501	Copper Development Association	OWN	
810.2300	Residual Self-Sanitizer Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048)	46999308	Copper Development Association	OWN	
810.2300	Residual Self-Sanitizer Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442)	46999309	Copper Development Association	OWN	
810.2300	Residual Self-Sanitizer Assay: <i>VRE. Faecalis</i> (ATCC 51575)	47859502	Copper Development Association	OWN	

Signature

Name and Title
Robert R. Stewart, Ph.D.Date
April 11, 2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

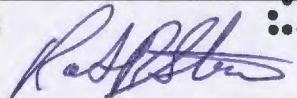
Form Approved OMB No. 2070-0060

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DATA MATRIX

Date April 11, 2013	EPA Reg. No./File Symbol 82012-3	Page 6 of 6
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016		Product Antimicrobial Copper Alloys Group III

Ingredient **Copper as elemental (PC Code 22501)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY (Cont.):					
810.2300	Repeat Challenge Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048)	46999304 46999311 46999313	Copper Development Association	OWN	
810.2300	Repeat Challenge Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442)	46999305	Copper Development Association	OWN	
810.2300	Repeat Challenge Assay: <i>VRE. Faecalis</i> (ATCC 51575)	47859503	Copper Development Association	OWN	
810.2300	Bioburden Reduction and Hospital Acquired Infection Reduction in Clinical Settings	This Submission	Copper Development Association	OWN	
Signature 			Name and Title Robert R. Stewart, Ph.D.		Date April 11, 2013

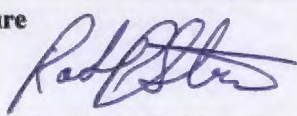


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Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY:					
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
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			Copper Development Association		Upon Request
			Copper Development Association	OWN	
			Copper Development Association	OWN	
Signature 		Name and Title Robert R. Stewart, Ph.D.		Date April 11, 2013	




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DATA MATRIX

Date April 11, 2013			EPA Reg. No./File Symbol 82012-3		Page 2 of 6
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016			Product Antimicrobial Copper Alloys Group III		
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY (Cont.):					
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
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			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
Signature 			Name and Title Robert R. Stewart, Ph.D.		Date April 11, 2013



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Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016	Product Antimicrobial Copper Alloys Group III	

Ingredient Copper as elemental (PC Code 22501)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY:					
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
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			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	

Signature 	Name and Title Robert R. Stewart, Ph.D.	Date April 11, 2013
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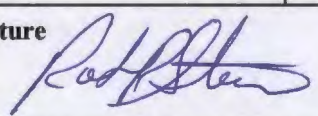


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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY (Cont.):					
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			Copper Development Association	OWN	
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			Copper Development Association	OWN	
Signature 			Name and Title Robert R. Stewart, Ph.D.		Date April 11, 2013



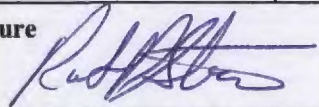
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Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY:					
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
Signature 			Name and Title Robert R. Stewart, Ph.D.		Date April 11, 2013



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY (Cont.):					
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	

Signature 	Name and Title Robert R. Stewart, Ph.D.	Date April 11, 2013
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ANTIMICROBIAL COPPER ALLOYS - GROUP III AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the Antimicrobial Alloys and a label that will accompany each product fabricated using a registered alloy from Antimicrobial Copper Alloys - Group III.

[Alloy Label – Front Panel]

ANTIMICROBIAL COPPER ALLOYS - GROUP III AND ASSOCIATED FABRICATED PRODUCTS

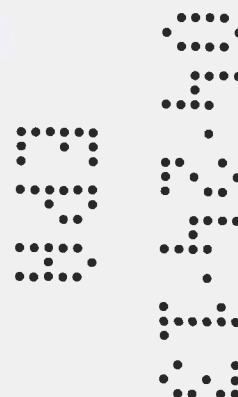
Active Ingredient:

Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *****
Distributed by *****

Net Weight: XXX lbs XXX ounces of [brand name]



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Antimicrobial Copper Alloys - Group III

These alloys are only intended for the manufacture and fabrication of touch surface components for use in hospitals, healthcare facilities, laboratories, and various public, commercial, and residential buildings. [The claims listed on the attached fabricated product label may be made in connection with the marketing and sale of Antimicrobial Copper Alloys - Group III and fabricated products made from Antimicrobial Copper Alloys - Group III under EPA Registration Number 82012-3.]

A list of components that may be fabricated out of Antimicrobial Copper Alloys - Group III is specified below. Antimicrobial Copper Alloys - Group III are not approved for direct food contact or food packaging uses.

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
 - Hospital carts (table surfaces, handles, legs)
 - Computer carts
 - Record carts
 - Phlebotomy carts
 - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors

- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles
 - Medical equipment knobs, pulls and handles for:
 - Drug delivery systems
 - Monitoring systems
 - Hospital beds
 - Office equipment
 - Operating room equipment
 - Stands and fixtures
 - Types of knobs: e.g., Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs
- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles

- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- Cup Holder
- Toothbrush holder
- Soap holder, dispenser
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates
- Medical equipment washers: exterior surfaces, housing, handles, pulls

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables
- Exercise equipment, handles, bars
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)

- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles

- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder, dispenser
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Laboratories

- Incubator interior and outside surfaces, including culture chambers, walls, shelving and support brackets, handles, circulating fan assemblies, pan
- Laboratory surfaces: table tops, counter tops, handles, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs
- Laboratory carts, trays, and pans
- Door handles, knobs, latches and locks
- Laboratory equipment: safety cabinets, enclosures, vent hoods

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring

- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

Do not wax, paint, lacquer, varnish, or otherwise coat touch surfaces.

Antimicrobial Copper Alloys - Group III – Fabricated Products

The Antimicrobial Copper Alloys - Group III fabricated products listed above may be sold and distributed under EPA Registration Number 82012-3. Products fabricated with Antimicrobial Copper Alloys - Group III must bear the EPA approved fabricated product label, below, with one or more of the listed claims.

STORAGE AND DISPOSAL

Dispose of excess by recycling.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

ANTIMICROBIAL COPPER ALLOYS - GROUP III

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from	
Antimicrobial Copper Alloys - Group III	
Active Ingredient:	
Copper	82.6%
Other.....	17.4%
[Total	100.0%]
See [Back/Side Panel][Insert] for Directions for Use	
Net Weight: XXX lbs XXX ounces of [brand name]	

BACK

ANTIMICROBIAL COPPER ALLOYS - GROUP I

Laboratory testing has shown that when cleaned regularly this surface:

- Continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure.
- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
- Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
- Kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations.
- Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.
- [This product/component name] is made (out of)(from) a (copper)(touch) surface that continuously kills bacteria left behind [by dirty hands][on the surface] killing more than 99.9% of bacteria within 2 hours.

* *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, *Pseudomonas aeruginosa* and, Vancomycin – Resistant *Enterococcus faecalis* (VRE).

Continuously reduces bacterial load [achieving 99.9% reduction within 2 hours].

Inhibits the growth of bacteria between [routine][scheduled] cleanings.

Kills [more than][>] 99.9% of bacteria within 2 hours.

Continuously kills bacteria left behind [on touch surface][by dirty hands][killing >99.9% of bacteria within 2 hours].

Bio-burden Reduction

Clinical trials have demonstrated that:

- Antimicrobial Copper touch surfaces [continuously] reduce the level of [Gram positive/ Gram negative] bacteria in healthcare facilities.
- The use of Antimicrobial Copper touch surfaces in healthcare facilities resulted in >80% average reduction in the level of [Gram positive/ Gram negative] bacteria.
- Antimicrobial Copper touch surfaces consistently reduced bacteria by >80%.
- Antimicrobial Copper touch surfaces deliver continuous and ongoing antibacterial action, remaining effective in killing >80% of bacteria.
- Antimicrobial Copper touch surfaces help inhibit the buildup and growth of bacteria between routine cleanings and sanitizing steps.
- [Touch surface][This product] Continuously reduces the bacterial load in healthcare settings,
- [More than][>] 80% reduction of bacteria on this surface [throughout the day].
- [This surface][brand name] reduces bacteria in healthcare settings.
- [This surface](brand name) Delivers continuous antibacterial action,
- Inhibits the buildup and growth of bacteria between cleanings.
- [This surface] [Continuously] Inhibits the growth of bacteria during active patient care.

Infection Reduction

Clinical trials have demonstrated that:

- Antimicrobial Copper touch surfaces kill bacteria resulting in a reduction in the number of hospital acquired infections.
- The use of Antimicrobial Copper touch surfaces in hospital intensive care rooms reduced the incidence of infection by more than 50%.
- Antimicrobial Copper touch surfaces [continuously] reduce the rate of infections in healthcare facilities.
- Patients treated in Intensive Care Units with Antimicrobial Copper touch surfaces had a >50% reduction in the incidence of infection [during active patient care].
- Antimicrobial Copper touch surfaces deliver continuous and ongoing antibacterial action, which has been proven to reduce the acquisition of infections.
- Antimicrobial Copper touch surfaces help inhibit the buildup and growth of bacteria between routine cleanings and sanitizing steps [during active patient care] which has been proven to reduce the acquisition of infections.
- Incorporating Antimicrobial Copper touch surfaces into infection control programs can reduce the incidence of infections.
- [Studies show that][This surface][brand name] continuously kills bacteria resulting in reduced hospital acquired infections.
- ICU infections reduced by [more than][>]50% when [antimicrobial [copper] touch surfaces][brand name] are installed.
- [This surface](brand name) Delivers continuous antibacterial action reducing infection [in healthcare settings].
- Hospital Acquired Infections (HAI) reduced when [antimicrobial copper touch surfaces] are used on high-touch surfaces.
- Reduce the incidence of [acquired] infections by [incorporating][using] antimicrobial touch surfaces in your infection control program.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. Clean and sanitize according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. ~~This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross-contamination.~~

This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

Not approved for direct food contact or food packaging uses.

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

KELLEY DRYE & WARREN LLP

A LIMITED LIABILITY PARTNERSHIP

WASHINGTON HARBOUR, SUITE 400

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April 24, 2013

Susan Lewis, Director
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C.

**Re: Antimicrobial Copper Alloys Groups III (EPA Reg. Nos. 82012-3)
Submission of Label Amendments (PRIA Category A570)**

Dear EPA and Director Lewis:

On behalf of the Copper Development Association (CDA), we are submitting the attached amendments to the registrations for Antimicrobial Copper Alloys Groups I-VI. The application is filed under PRIA category A570 as an amended registration requiring review of efficacy data with no increased or new exposure scenarios. On February 29, 2008, CDA received EPA approval of public health registrations for five groups of "Antimicrobial Copper Alloys" (EPA Reg. Nos. 82012-1 to -5) (a sixth group, EPA Reg. No 82012-6, was registered in 2009), each containing 60%-99.9% copper, for use in manufacturing a variety of touch surfaces in healthcare facilities, community buildings, and homes. The registrations were the culmination of a five-plus year process of research to demonstrate the efficacy of these products and working with the EPA to address various policy and practical implications of this novel antimicrobial product. As the first solid, continuously active touch surface registered for public health applications, the labeling of Antimicrobial Copper Alloys was carefully crafted with EPA to ensure that users were well-informed about the proper role of the product as a supplement to – but not a replacement for – routine cleaning and sanitizing programs.

Prior to registration, EPA required CDA to conduct outreach to experts in the infection control community, including the Association for Professionals in Infection Control and Epidemiology ("APIC"), the American Society for Healthcare Environmental Services ("ASHES"), Dr. William Rutala from the University of North Carolina-Chapel Hill, and others. The input received was critical in shaping the conditions and requirements of the registration. The issues raised included questions about the real world efficacy of the product and the need for

- ▶ Sustained Reduction of Microbial Burden on Common Hospital Surfaces through Introduction of Copper, by Michael G. Schmidt, et. al., July 2012 Volume 50 Number 7 Journal of Clinical Microbiology, p. 2217-2223
- ▶ Copper Continuously Limits the Concentration of Bacteria Resident on Bed Rails within the Intensive Care Unit, Michael G. Schmidt, et. al., Infection Control and Hospital Epidemiology, May 2013, vol. 34, no. 5, p. 530-533
- ▶ Copper Surfaces Reduce the Rate of Healthcare-Acquired Infections in the Intensive Care Unit, Cassandra D. Salgado, et. al., Infection Control and Hospital Epidemiology, May 2013, vol. 34, no. 5, p. 479-486

Based on the clinical trial data, as well as information from other studies related to antimicrobial copper alloys discussed in the application package, CDA seeks to amend the registrations for Antimicrobial Copper Alloys Groups I-VI in the following ways:

- ▶ Add claims related to the microbial (bio-) burden reduction identified in the clinical setting.
- ▶ Add claims related to the reduction in infection rates documented in the clinical trials.
- ▶ Remove the existing label statement "The Copper Alloy surface material has been shown to reduce microbial contamination, but it does not necessarily prevent cross contamination." The clinical trials demonstrate that Antimicrobial Copper Alloys in fact help reduce cross contamination and infection rates. At minimum, the study makes clear that it is inappropriate to require Antimicrobial Copper Alloys to state affirmatively that the product does not help reduce cross contamination, while other antimicrobial products are not required to do the same.

Given the novel nature of the issues raised in the application, we believe that a meeting with the EPA Antimicrobials Division would be appropriate. To assist in evaluating the proposed claims and registration amendment application, CDA has developed a white paper explaining the rationale and support for the claims, including detailed information on the association between a given level of microbial contamination and the risk of infection. While we understand that EPA may have never approved infection-related claims, there is no legal barrier to the agency doing so.² Rather, historically the agency has not been presented with clinical trial data from a high quality study, such as that conducted by CDA and the Department of Defense,

² EPA's Label Review Manual (Chapter 12 at 12-2) notes that examples of unacceptable claims are "Statements that imply or suggest that the product can or will prevent or control disease or offer health protection." Claims based on data from well-designed clinical trials showing that infection rates can be reduced through the use of Antimicrobial Copper Alloys are not disease control or prevention claims. Rather, the claims proposed in the application are based on data that show that reduction in microbial burden leads to reduced risk of infection (not prevention of infection) as supported by the clinical trial data. Claims that are consistent with the results of a well-designed clinical trial are neither false nor misleading and, as such, are appropriate under FIFRA.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 82012-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Antimicrobial Copper Alloys Group III	PM# 33	
5. Name And Address Of Applicant (Include ZIP Code) Copper Development Association Inc. 260 Madison Avenue New York, NY 10016 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input checked="" type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)**Submission of an amendment to add claims requiring the review of data. PRIA category A570.****Section III**

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u>none</u>
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Packaging wgt. No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(S) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

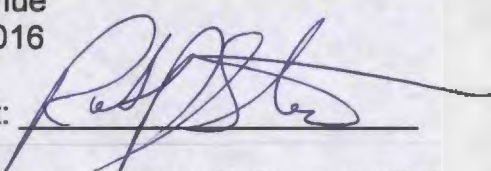
Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Robert R. Stewart, Ph.D.	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8963
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant to Copper Development Association Inc.	
4. Typed Name Robert R. Stewart, Ph.D.	5. Date April 13, 2013	

TRANSMITTAL DOCUMENT

Submitter:

Copper Development Association
260 Madison Avenue
New York, NY 10016

Company Contact: 

Typed Name of Signer: Robert R. Stewart, Ph.D.

Phone: 202-828-8963

Fax: 202-872-0745

Email address: rstewart@tsgusa.com

Regulatory Action in Support of Which this Package is Submitted:

EPA registration numbers: 82012-1 through 6,
Antimicrobial Copper Alloys, Groups 1 through 6
Amendment to add Clinical Claims to the labels

Submission date:

April 24, 2013

List of Submitted Documents:

Volume 1 Administrative materials for Antimicrobial Copper Alloys
Groups 1 through 6 (6 Administrative Volumes)

Including:

Cover letter

PRIA receipt

Application Form,

Data Certification with Matrices (confidential and non-confidential)

One copy of the proposed label with highlighted changes

Five (5) copies of the proposed label

Volume 2

Patton, L., April 15, 2013, Clinical Trial of the Use of Antimicrobial Copper Alloys in Reducing the Amount of Bacteria on Touch Surfaces in Hospital Intensive Care Units and the Effect on the Number of Hospital Acquired Infections, Technology Sciences Group Inc., Report No. 2013 CDA1.

Receipt for Section 3

S: 934416

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 92012 COPPER DEVELOPMENT ASSOCIATION (CDA) V

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 92012-3

Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP I

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 15-Apr-2013

Front End Date: 25-Apr-2013

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description: AMENDMENT WITH STUDIES

Form A:

Signature Date:

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

OPP Rec'd Date: 24-Apr-2013

Risk Manager Send Date:

Negotiated Due Date:

New Ingredient:

New Ingredient Request Date:

New Ingredient Received Date:

Form B:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

Paper Label

View/Edit

Fee for Service

{9344184~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr.

33

Receipt No.

S-

934418

EPA File Symbol/Reg. No.

82012-3

Pin-Punch Date:

4/25/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A570

Granted: A570

Amount Due: \$3,474.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team Two

Date: 04-29-13

Remarks:

DECISION PKG. NO. 82012-3
SUBMISSION BAR CODE # 931437

SUBM. DUE DATE 3/24/13
REVIEWER Z. THASAK

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 82012-3 PM 33 ACTION CODE 332

DESCRIPTOR Label NOT. Piction **FQPA** **NFQPA**

☐ CHILD RESISTANT PACKAGING; ☐ REQUIRED ☐ NOT REQUIRED
REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

2, 15, 13

EPA RECEIVE DATE

2, 22, 13

PM RECEIVE DATE

2, 5, 13

METHOD OF SUPPORT

☐ CITE-ALL ☐ SELECTIVE
☐ NOT SUBMITTED ☐ N/A

FORMULATORS EXEMPTION

☐ SUBMITTED ☐ NOT SUBMITTED
☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #

DATE
SENT

DUE
DATE

DATE
RETURNED

CHEMISTRY _____

EFFICACY _____

ACUTE TOX. _____

RASSB TOX. _____

ENVIRON. FATE _____

FISH/WILDLIFE _____

OTHER: _____

STATUS _____

RESPONSE CODE _____

RESPONSE DATE _____

SCIENCE
GROUP

DIVISION

BRANCH

SECTION

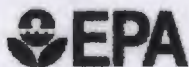
CSF
Y/N

LABEL
Y/N

CHEMISTRY AD EASSB CTT

EFFICACY AD EASSB EET

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Copper Development Association
260 Madison Avenue
New York, NY
10016

MAR 21 2013

Attention: Joseph J. Green

Subject: ANTIMICROBIAL COPPER ALLOYS-GROUP III
EPA Registration No: 82012-3
Notification Dated: February 15, 2013

This will acknowledge receipt of your notification, submitted under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(c) (9).

Proposed Notification

- To add additional new use sites on the product label

General Comments

Base on a review of the submitted material, the following comments apply:

The Notification dated February 15, 2013, is compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely

A handwritten signature in black ink, appearing to read "M. Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobial's Division (7501P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82012-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Antimicrobial Copper Alloys Group III	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Copper Development Association, Inc. 260 Madison Avenue, New York, NY 10016 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of additional use sites per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt.	No. per container	<input checked="" type="checkbox"/> Other (Specify) <u>None</u>	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container n/a no container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other <u>Attached to Bill of Lading</u>			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Joseph J. Green		Title Counsel to CDA	
		Telephone No. (Include Area Code) 202.342.8849	
<p align="center">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>			
2. Signature 		3. Title Counsel to Copper Development Assoc.	
4. Typed Name Joseph J. Green		5. Date February 15, 2013	
6. Date Application Received (Stamped)			

ANTIMICROBIAL COPPER ALLOYS - GROUP III AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the Antimicrobial Alloys and a label that will accompany each product fabricated using a registered alloy from Antimicrobial Copper Alloys - Group III.

[Alloy Label – Front Panel]

ANTIMICROBIAL COPPER ALLOYS - GROUP III AND ASSOCIATED FABRICATED PRODUCTS

Active Ingredient:

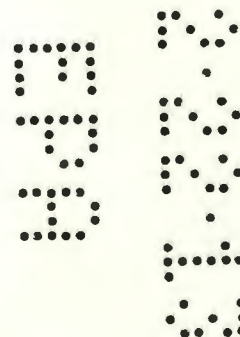
Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *****
Distributed by *****

Net Weight: XXX lbs XXX ounces of [brand name]

NOTIFICATION
Date Reviewed: 3/8/13
Reviewed By: [Signature]



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Antimicrobial Copper Alloys - Group III

These alloys are only intended for the manufacture and fabrication of touch surface components for use in hospitals, healthcare facilities, **laboratories**, and various public, commercial, and residential buildings. [The claims listed on the attached fabricated product label may be made in connection with the marketing and sale of Antimicrobial Copper Alloys - Group III and fabricated products made from Antimicrobial Copper Alloys - Group III under EPA Registration Number 82012-3.]

A list of components that may be fabricated out of Antimicrobial Copper Alloys - Group III is specified below. Antimicrobial Copper Alloys - Group III are not approved for direct food contact or food packaging uses.

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
 - Hospital carts (table surfaces, handles, legs)
 - Computer carts
 - Record carts
 - Phlebotomy carts
 - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, **drain fittings** (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors



- Towel bars
- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

Medical equipment knobs, pulls and handles for:

- Drug delivery systems
- Monitoring systems
- Hospital beds
- Office equipment
- Operating room equipment
- Stands and fixtures

Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs

- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles

- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- Cup Holder
- Toothbrush holder
- Soap holder, **dispenser**
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates
- **Medical equipment washers: exterior surfaces, housing, handles, pulls**

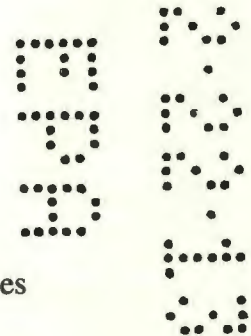
Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables
- **Exercise equipment, handles, bars**
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)

- Single and double-hung windows (locks and pulls)
- Light switches, switch plates
- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles



- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder, **dispenser**
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Laboratories

- Incubator interior and outside surfaces, including culture chambers, walls, shelving and support brackets, handles, circulating fan assemblies, pan
- Laboratory surfaces: table tops, counter tops, handles, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs
- Laboratory carts, trays, and pans
- Door handles, knobs, latches and locks
- Laboratory equipment: safety cabinets, enclosures, vent hoods

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring

- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

Do not wax, paint, lacquer, varnish, or otherwise coat touch surfaces.

Antimicrobial Copper Alloys - Group III – Fabricated Products

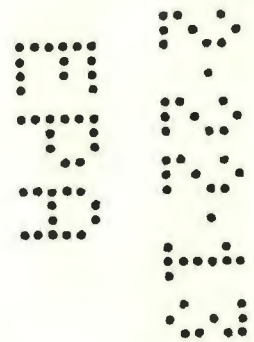
The Antimicrobial Copper Alloys - Group III fabricated products listed above may be sold and distributed under EPA Registration Number 82012-3. Products fabricated with Antimicrobial Copper Alloys - Group III must bear the EPA approved fabricated product label, below, with one or more of the listed claims.

STORAGE AND DISPOSAL

Dispose of excess by recycling.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.



ANTIMICROBIAL COPPER ALLOYS - GROUP III

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from

Antimicrobial Copper Alloys - Group III

Active Ingredient:

Copper82.6%

Other..... 17.4%

[Total 100.0%]

See [Back/Side Panel][Insert] for Directions for Use

Net Weight: XXX lbs XXX ounces of [brand name]

BACK

ANTIMICROBIAL COPPER ALLOYS - GROUP III

Laboratory testing has shown that when cleaned regularly this surface:

- Continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure.
 - Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
 - Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
 - Kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations.
 - Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.
 - [This product/component name] is made (out of)(from) a (copper)(touch) surface that continuously kills bacteria left behind [by dirty hands][on the surface] killing more than 99.9% of bacteria within 2 hours.
- * *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, *Pseudomonas aeruginosa* and, Vancomycin - Resistant *Enterococcus faecalis* (VRE).

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. Clean and sanitize according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

Not approved for direct food contact or food packaging uses.

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impact reduced efficacy if not cleaned when visibly soiled.]

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 82012-3

EPA Est. No. [Product Manufacturer Number] 82012-NY-001

Manufactured by: [Product Manufacturer Company Name and Address]

Copper Development Association, 260 Madison Ave., NY, NY 10016-240

Receipt for Section 3

S: 931437

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 82012 COPPER DEVELOPMENT ASSOCIATION (CDA)

V

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 82012-3

Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP I

Overturn#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 15-Feb-2013

id

OPP Rec'd Date: 22-Feb-2013

id

Front End Date: 22-Feb-2013

id

Risk Manager Send Date: 22-Feb-2013

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Notification of additional use sites per PR Notice 98-10

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Paper Label

View/Edit

New Ingredient

Request Date:

New Ingredient

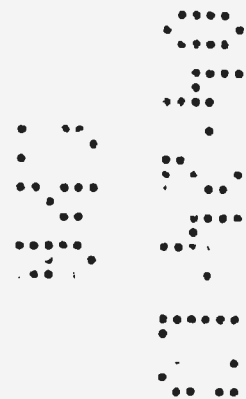
Received Date:

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25AD3BDQ
Agency Tracking ID: 74437471675
Transaction Type: Sale
Transaction Date: Apr 17, 2013 12:15:13 PM

Account Holder Name: Marie E. Yetzetta
Transaction Amount: \$3,474.00
Billing Address: 260 Madison Ave.
Billing Address 2: 16th FL
City: New York
State/Province: NY
Zip/Postal Code: 10016
Country: USA
Card Type: AmericanExpress
Card Number: *****1012

Decision Number:
Registration Number: 82012-3
Company Name: Copper Development Associ
Company Number: 82012
Action Code: A570





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 29, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-478065
EPA File Symbol or Registration Number: 82012-3
Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP III
EPA Receipt Date: 24-Apr-2013
EPA Company Number: 82012
Company Name: COPPER DEVELOPMENT ASSOCIATION (CDA)

JOSEPH J. GREEN
KELLEY DRYE & WARREN LLP
COPPER DEVELOPMENT ASSOCIATION (CDA)
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;REQUIRING DATA REVIEW;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in black ink, appearing to be "m/2k".

Front End Processing Staff
Information Technology & Resources Management Division

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4-24-13

Experts In-Processing Signature: B.R.

Date 4-30-13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>82012-3</u>		EPA Receipt Date: <u>4-24-13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)					X
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Passed 11-3 review, MRID 491085

JD 5/1/13

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

DECISION PKG. NO.

469131

SUBM. DUE DATE

11/19/12
10/18/2012

SUBMISSION BAR CODE #

919845

REVIEWER

R Leary**CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS**

FILE SYMBOL/REG NO.

82012-3PM 33

ACTION CODE

3/2

DESCRIPTOR

CSF Amendment**FQPA****NFQPA**☐ CHILD RESISTANT PACKAGING;☐ REQUIRED☐ NOT REQUIRED

REGISTRATION TYPE:

☐ CONDITIONAL☐ UNCONDITIONAL☐ RESTRICTED USE

DATE ON APPLICATION

8, 29, 12

EPA RECEIVE DATE

8, 29, 12

PM RECEIVE DATE

8, 29, 2012

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL☐ SELECTIVE☐ SUBMITTED☐ NOT SUBMITTED☐ NOT SUBMITTED☐ N/A☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

ACUTE TOX.

RASSB TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER:

STATUS

RESPONSE CODE

RESPONSE DATE

SCIENCE
GROUP

DIVISION

BRANCH

SECTION

CSF
Y/NLABEL
Y/N

CHEMISTRY

AD

EASSE

CTT

EFFICACY

AD

EASSE

ERT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV - 7 2012

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Micah Reynolds
Regulatory Assistant for,
c/o Copper Development Association
Technology Sciences Group, Inc.
1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036

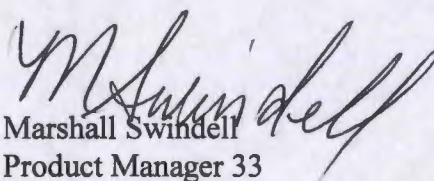
Subject: Antimicrobial Copper Alloys Group III
EPA Registration Number 82012-3
Your Amendment Dated August ~~20~~, 2012
EPA Received Date August ~~21~~, 2012

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add additional inert components to the product formulation, is acceptable.

The Confidential Statement of Formula dated August 1st, 2012, for the basic formulation is acceptable.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,


Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

November 2, 2012

DP BARCODE: 404955

MRID : 48899101

SUBJECT: Antimicrobial Copper Alloys-Group III
(Name of Product)

REG. NO.: 82012-3

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use []

OR

End-use Product [x]

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
022501	7440-50-8	Copper (metallic)

TEST LAB: NA

SUBMITTER: Copper Development Association (CDA)

GUIDELINE: OPPTS 830.1750

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVER: Karen P. Hicks

APPROVED DATE: November 2, 2012

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

Antimicrobials Division (AD)

November 2, 2012

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 82012-3
Product Name: Antimicrobial Copper Alloys-Group III
DP Barcode: 404955

CODE: (362) Formulation Change; Technical

DATE DUE: September 2, 2012

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Copper Development Association (CDA)

PRODUCT FORMULATION FROM LABEL:

<u>PC Codes</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
022501	Copper (metallic)	82.6
	<u>Other Ingredient(s):</u>	17.4
	Total:	100.0

BACKGROUND:

Technology Sciences Group Inc. as the agent on behalf of the registrant Copper Development Association has submitted a request to amend the registration of this product. The amendment is to add 17 additional alternative alloys. After this amendment is accepted, the total number of alloys for this product will increase to 74 alternate alloy formulations. Each alternate alloy is identified with its own UNS number (Unified Numbering System) and the percent copper in the alloy. UNS is an identification system established by ASTM and the Society of Automotive Engineers.

The product consists of alloys of copper which are intended for use in the manufacture and fabrication of touch surface components (doorknobs, handrails, etc) for use in hospitals, healthcare facilities, and various public, commercial, and residential buildings.

This submission includes:

1. Transmittal Letter dated August 3, 2012.
2. Group A Chemistry MRID# 48899101 consisting of a revised OPPTS 830.1750 (Certified Limits) study which is dated August 2, 2012. This is an update of the previous MRID# 482362-01
3. Basic CSF dated August 1, 2012 consists of 9 pages. Pages 1 & 2 EPA form 8570-4 describes the active ingredient and [REDACTED] alternate elemental "inert" ingredients used to formulate the alloys. Other pages list UNS designations of 74 alloys and their % Copper, lists of 5 alloy producers and lists suppliers of the inert ingredients used to formulate the alloys.

FINDINGS:

1. The nominal concentrations and certified limits on the copper a.i. and the certified limits on the inert ingredients are acceptable. The nominal concentration of copper is consistent with the current product label. The upper certified limits for 4 of the inert elements are increased and 3 new acceptable elements are added. The Basic Confidential Statement of Formula which is dated August 1, 2012 is found acceptable.
2. Revisions made to the Group A Product Chemistry section OSCPP 830.1750 (Certified Limits) are consistent with the revised Basic CSF dated August 1, 2012 and is found acceptable to supersede the previous submission for this product chemistry section.

CONCLUSION:

The basic CSF dated August 1, 2012 is acceptable and must supersede previous versions. The revised Product Chemistry Group A section OCSP 830.1750 MRID # 48899101 is also acceptable.

DATA PACKAGE BEAN SHEET

Date: 29-Aug-2012

Page 1 of 1

Decision #: 469131

DP #: (404955)

NON PRIA

Parent DP #:

Submission #: 921421

E-Sub #:

*** Registration Information ***

Registration: **82012-3 - ANTIMICROBIAL COPPER ALLOYS - GROUP III**

Company: **82012 - COPPER DEVELOPMENT ASSOCIATION (CDA)**

Risk Manager: **RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828**

Risk Manager Reviewer: **Karen Leavy KLEAVY**

Sent Date: _____

PRIA Due Date: **02-Sep-2012**

Edited Due Date: _____

Type of Registration: **Product Registration - Section 3**

Action Desc: **(332) NOTIFICATION;**

Ingredients: **022501, Copper as elemental(82.6%)**

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: **29-Aug-2012**

Due Back: _____

DP Ingredient: **022501, Copper as elemental**

DP Title: **Amendment**

CSF Included: ☒ Yes ☐ No

Label Included: ☐ Yes ☒ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: **AD / PSB**

Last Possible Science Due Date: **18-Aug-2012**

Team Name: **CTT**

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the attached Product Chemistry data and CSF



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date	August 2, 2012	EPA Reg. No./File Symbol	82012-3	Page 1 of 6	
Applicant's/Registrant's Name & Address:	Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016	Product	Antimicrobial Copper Alloys Group III		
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY:					
830.1550	Product Identity and Composition	46999301 47259201	Copper Development Association	OWN	
830.1600	Description of Materials Used to Produce the Product	46999301	Copper Development Association	OWN	
830.1620	Description of Production Process	46999301	Copper Development Association	OWN	
830.1650	Description of Formulation Process	46999301	Copper Development Association	OWN	
830.1670	Discussion of Formation of Impurities	46999301	Copper Development Association	OWN	
830.1700	Preliminary Analysis	46999301 47160802	Copper Development Association	OWN	
830.1750	Certification of Limits	This Submission	Copper Development Association	OWN	
830.1800	Enforcement Analytical Methods	46999301	Copper Development Association	OWN	
830.1900	Submittal of Samples	46999301	Copper Development Association		Upon Request
830.6302	Color	47160801	Copper Development Association	OWN	
830.6303	Physical State	47160801	Copper Development Association	OWN	
Signature			Name and Title Micah T. Reynolds, Regulatory Consultant	Date August 2, 2012	

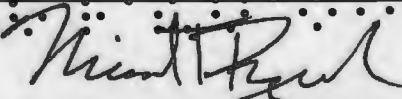


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WASHINGTON, D.C. 20460

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DATA MATRIX

Date August 2, 2012			EPA Reg. No./File Symbol 82012-3	Page 2 of 6	
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016			Product Antimicrobial Copper Alloys Group III		
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY (Cont.):					
830.6304	Odor	47160801	Copper Development Association	OWN	
830.6314	Oxidizing or Reducing Action	47160801	Copper Development Association	OWN	
830.6315	Flammability	47160801	Copper Development Association	OWN	
830.6316	Explosibility	47160801	Copper Development Association	OWN	
830.6317	Storage Stability	47160801	Copper Development Association	OWN	
830.6319	Miscibility	47160801	Copper Development Association	OWN	
830.6320	Corrosion Characteristics	47160801	Copper Development Association	OWN	
830.6321	Dielectric Breakdown Voltage	47160801	Copper Development Association	OWN	
830.7000	pH	47160801	Copper Development Association	OWN	
830.7100	Viscosity	47160801	Copper Development Association	OWN	
830.7300	Density, Bulk Density or Specific Gravity	47160801	Copper Development Association	OWN	
Signature 			Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012



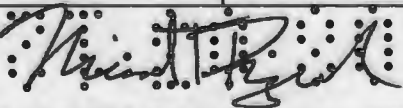
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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date August 2, 2012			EPA Reg. No./File Symbol 82012-3	Page 3 of 6	
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016			Product Antimicrobial Copper Alloys Group III		
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY:					
870.1100	Acute Oral Toxicity: Rat	46999302	Copper Development Association	OWN	
870.1200	Acute Dermal Toxicity: Rat	46999302	Copper Development Association	OWN	
870.1300	Acute Inhalation Toxicity: Rat	46999302	Copper Development Association	OWN	
870.2400	Primary Eye Irritation: Rabbit	46999302	Copper Development Association	OWN	
870.2500	Primary Dermal Irritation	46999302	Copper Development Association	OWN	
870.2600	Dermal Sensitization	46999302	Copper Development Association	OWN	
870.3100	90-Day Oral Toxicity	46999302	Copper Development Association	OWN	
870.3150	90-Day Oral Toxicity – Nonrodent	46999302	Copper Development Association	OWN	
870.3250	90-Day Dermal Toxicity	46999302	Copper Development Association	OWN	
870.3700	Teratology – Rats	46999302	Copper Development Association	OWN	
870.3700	Teratology – Rabbits	46999302	Copper Development Association	OWN	
Signature 			Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version



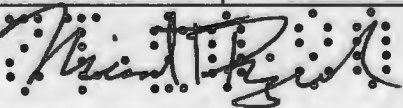
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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date August 2, 2012			EPA Reg. No./File Symbol 82012-3		Page 4 of 6
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016			Product Antimicrobial Copper Alloys Group III		
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY (Cont.):					
870.3800	Reproduction and Fertility Effects	46999302	Copper Development Association	OWN	
870.4100	Chronic Oral/Feeding Study	46999302	Copper Development Association	OWN	
870.5100	Bacterial Reverse Mutation (Ames) Test	46999302	Copper Development Association	OWN	
870 Genotoxicity Series	Other Mutagenicity	46999302	Copper Development Association	OWN	
870.7485	Metabolism and Pharmacokinetics - Rat	46999302	Copper Development Association	OWN	
Signature 			Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012

EPA Form 8570-35 (9-97) Electronic and Paper Versions Available. Submit only Paper version.



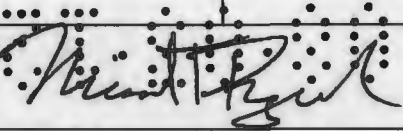
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date August 2, 2012		EPA Reg. No./File Symbol 82012-3		Page 5 of 6	
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016		Product Antimicrobial Copper Alloys Group III			
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY:					
810.2300	Hard Surface Sanitizer Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048)	46999306 46999310 46999312	Copper Development Association	OWN	
810.2300	Hard Surface Sanitizer Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442)	46999307	Copper Development Association	OWN	
810.2300	Hard Surface Sanitizer Assay: <i>VRE. Faecalis</i> (ATCC 51575)	47859501	Copper Development Association	OWN	
810.2300	Residual Self-Sanitizer Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048)	46999308	Copper Development Association	OWN	
810.2300	Residual Self-Sanitizer Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442)	46999309	Copper Development Association	OWN	
810.2300	Residual Self-Surface Sanitizer Assay: <i>VRE. Faecalis</i> (ATCC 51575)	47859502	Copper Development Association	OWN	
Signature: 		Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012	

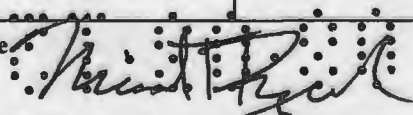


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DATA MATRIX

Date August 2, 2012		EPA Reg. No./File Symbol 82012-3		Page 6 of 6	
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016		Product Antimicrobial Copper Alloys Group III			
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
EFFICACY (Cont.):					
810.2300	Repeat Challenge Assay: <i>S. aureus</i> (ATCC 6538); <i>E. aerogenes</i> (ATCC 13048)	46999304 46999311 46999313	Copper Development Association	OWN	
810.2300	Repeat Challenge Assay: <i>MRS. aureus</i> (ATCC 33592); <i>E. coli</i> (ATCC 35150); <i>P. aeruginosa</i> (ATCC 15442)	46999305	Copper Development Association	OWN	
810.2300	Repeat Challenge Assay: <i>VRE. Faecalis</i> (ATCC 51575)	47859503	Copper Development Association	OWN	
Signature 			Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012

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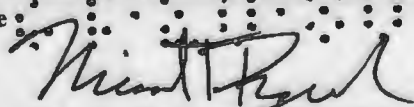
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DATA MATRIX

Date August 2, 2012	EPA Reg. No./File Symbol 82012-3	Page 1 of 6
Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016	Product Antimicrobial Copper Alloys Group III	

Ingredient Copper as elemental (PC Code 22501)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association		Upon Request
			Copper Development Association	OWN	
			Copper Development Association	OWN	

Signature: 	Name and Title Micah T. Reynolds, Regulatory Consultant	Date August 2, 2012
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DATA MATRIX

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Applicant's/Registrant's Name & Address:	Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016	Product	Antimicrobial Copper Alloys Group III	

Ingredient **Copper as elemental (PC Code 22501)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
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			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
Signature				Name and Title Micah T. Reynolds, Regulatory Consultant	Date August 2, 2012




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DATA MATRIX

Date August 2, 2012			EPA Reg. No./File Symbol 82012-3		Page 3 of 6
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			Copper Development Association	OWN	
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			Copper Development Association	OWN	
			Copper Development Association	OWN	
Signature: 			Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012




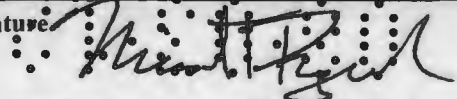
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Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016			Product Antimicrobial Copper Alloys Group III		
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
Signature: 			Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012

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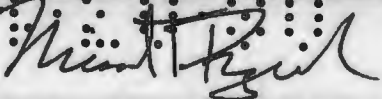


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Applicant's/Registrant's Name & Address: Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016		Product Antimicrobial Copper Alloys Group III			
Ingredient Copper as elemental (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	
Signature 			Name and Title Micah T. Reynolds, Regulatory Consultant		Date August 2, 2012



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date	August 2, 2012	EPA Reg. No./File Symbol	82012-3	Page 6 of 6
Applicant's/Registrant's Name & Address:	Copper Development Association, Inc. 260 Madison Avenue New York, New York 10016	Product	Antimicrobial Copper Alloys Group III	

Ingredient Copper as elemental (PC Code 22501)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Copper Development Association	OWN	
			Copper Development Association	OWN	
			Copper Development Association	OWN	

Signature		Name and Title	Micah T. Reynolds, Regulatory Consultant	Date	August 2, 2012
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2137T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

Copper Development Association

260 Madison Avenue

New York, New York 10016 Tel: (202) 828-8967

EPA Registration Number/File Symbol

82012-3

Active Ingredient(s) and/or representative test compound(s)

Copper, metallic (PC Code 22501)

Date

August 2, 2012

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)

Indoor, Non-Food

Product Name

Antimicrobial Copper Alloys Group III

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27)



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Micah T. Reynolds

Date

August 2, 2012

Typed or Printed Name and Title

Micah T. Reynolds, Regulatory Consultant

**Technology Sciences Group Inc.**

1150 18th Street, Suite 1000
 Washington, DC 20036
 Direct: (202) 828-8967
 Fax: (202) 872-0745
 E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
 Regulatory Consultant

August 3, 2012

Copper Development Association, Inc.
**Submission of Minor Formulation Amendment/
 CSF Revision for Antimicrobial Copper Alloys
Group III, EPA Reg. No. 82012-3**

Mr. Marshall Swindell, PM-33
 Antimicrobials Division (7504P)
 Office of Pesticide Programs
 U.S. Environmental Protection Agency
 Document Processing Center
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, Virginia 22202

Dear Mr. Swindell:

Technology Sciences Group, Inc., on behalf of Copper Development Association (CDA), is submitting the enclosed minor formulation amendment with CSF revision for the above-referenced product. CDA is seeking to revise the current CSF with additional copper alloy materials. A supplemental chemistry study accompanies this formulation amendment to assist the review process. Please find enclosed the following documents supporting this response:

- 1) EPA Application for Amendment (EPA Form 8570-1) with Transmittal Document;
- 2) Certification with Respect to Citation of Data (EPA Form 8570-34);
- 3) Data Matrix, Confidential and Releasable versions (EPA Form 8570-35);
- 4) Current Confidential Statement of Formula (EPA Form 8570-4) (1 copy);
- 5) Proposed Revised Confidential Statement of Formula (2 copies);
- 6) Supporting Reference Study Volume – Certified Limits (3 copies).

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,

Regulatory Consultant to
 Copper Development Association, Inc.

Enclosures

Washington, D.C.
 1150 18th St., NW, Suite 1000
 Washington, D.C. 20036
 Phone: (202) 223-4392

California
 712 Fifth St., Suite A
 Davis, CA 95616
 Phone: (530) 757-1245

Canada
 275 Slater St., Suite 900
 Ottawa, Ontario K1P 5H9
 Phone: (613) 247-6285

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant)

EPA Company No. 82012

Copper Development Association
260 Madison Avenue
New York, NY 10016

Authorized Representative:

Micah T. Reynolds
Technology Sciences Group, Inc.
1150 18th Street, NW, Suite 1000
Washington, DC 20036
Tel: (202) 828-8967

2. Regulatory Action for which this Package is Submitted:

Non-PRIA, Fast-Track, Minor Formulation Amendment/Revised Confidential Statement of Formula supporting the addition of copper alloys to Antimicrobial Copper Alloys Group III (EPA Reg. No. 82012-3)

3. Transmittal Date

August 3, 2012

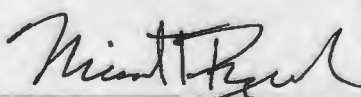
4. List of Submitted Documents


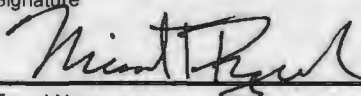
MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 2	<u>Administrative Materials</u> Cover Letter; Application for Amendment; Transmittal Document; Certification with Respect to Citation of Data; Data Matrix – confidential & sanitized versions Current Confidential Statement of Formula (1 copy) Proposed Confidential Statement of Formula (2 copies)	
<u>48899101</u>	2 of 2	Antimicrobial Copper Alloys Group III Supplemental Product Chemistry	830.1750

5. Company Contact

Company Name: Copper Development Association Inc.

Authorized Representative:


Micah T. Reynolds
Regulatory Consultant
Technology Sciences Group, Inc.
Email: mreynolds@tsgusa.com
Telephone: (202) 828-8967
FAX: (202) 872-0745

		United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other		OPP Identifier Number	
Application for Pesticide – Section I							
1. Company/Product Number 82012-3				2. EPA Product Manager Marshall Swindell		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Antimicrobial Copper Alloys Group III				PM# 33			
5. Name And Address Of Applicant (Include ZIP Code) Copper Development Association Inc. 260 Madison Avenue New York, NY 10016 <input type="checkbox"/> Check if this is a new address				6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
Section II							
<input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Notification – Explain below. <input type="checkbox"/> Other – Explain Below.							
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Submission of Non-PRIA Fast-Track, Minor Formulation Amendment/Revised Confidential Statement of Formula for this product per PR Notice 98-10. Please confirm receipt with Micah Reynolds: mreynolds@tsgusa.com, via phone (202) 828-8967, or via fax (202) 872-0745.							
Section III							
1. Material This Product Will Be Packaged In:							
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container		2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>none</u>	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container N/A – no container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <u>Attached to Bill of Lading</u>							
Section IV							
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)							
Name Micah T. Reynolds, Technology Sciences Group, Inc.			Title Regulatory Consultant		Telephone No. (Include Area Code) (202) 828-8967		
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.						6. Date Application Received (Stamp) 	
2. Signature 			3. Title Regulatory Consultant to Copper Development Association Inc.				
4. Typed Name Micah T. Reynolds			5. Date August 3, 2012				

Receipt for Section 3

S: 821421

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 82012 COPPER DEVELOPMENT ASSOCIATION (CDA)

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 82012-3 Product Name: ANTIMICROBIAL COPPER ALLOYS - GROUP 1

Me Too Section3: Me Too Product Name:

Application Date: 03-Aug-2012 OPP Rec'd Date: 03-Aug-2012

Front End Date: 03-Aug-2012 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: New Ingredient:

Receipt Description: CSF Amendment with Studies.

Form A Signature Date: Form B Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study	Des
CSF	

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

[362-KL]
Send to Chem

Receipt for Section 3

S: Resubmission: ☐ Yes ☒ No

Regulatory Type: Fee For Service: ☐ Yes ☒ No

Application Type: Billable: ☐ Yes ☒ No

Company: ☒ V

Risk Manager:

Product #: Product Name:

Override#:

Me Too Me Too

Section3: Product Name:

Application Date: OPP Rec'd Date:

Front End Date: Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content

Study	
CSF	

View/Edit

Print Letter

Enter More Information

Tracking



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 8, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JOSEPH J. GREEN
KELLEY DRYE & WARREN LLP
COPPER DEVELOPMENT ASSOCIATION (CDA)
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007-

PRODUCT NAME: ANTIMICROBIAL COPPER ALLOYS - GROUP III
COMPANY NAME: COPPER DEVELOPMENT ASSOCIATION (CDA)
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 82012-3
EPA RECEIPT DATE: 08/03/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-6341.

Sincerely,

A handwritten signature in blue ink, appearing to be "Sejv", is located below the "Sincerely," text.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

M
{921421k~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr.

33

Receipt No.

S- **921421**

EPA File Symbol/Reg. No.

82012-3

Pin-Punch Date:

8/3/2012

☒ This item is NOT subject to FFS action.

Action Code:

Requested: **A570**

Granted: **A570**

Amount Due: \$ **3,474**

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team 3

Date: 8/6/2012

Remarks:

Receipt for Section 3					
S:	898916		Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Regulatory Type:	Product Registration - Section 3		Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Application Type:	Notification				
Company:	82012 COPPER DEVELOPMENT ASSOCIATION (CDA)		<input checked="" type="checkbox"/>		
Risk Manager:	Antimicrobials Division, Risk Management Team 33				
Product #:	82012-3	Product Name:	ANTIMICROBIAL COPPER ALLOYS - GROUP I		
Override#:					
Me Too Section3:		Me Too Product Name:			
Application Date:	28-Jun-2011	icd	OPP Rec'd Date:	01-Jul-2011	icd
Front End Date:	01-Jul-2011	icd	Risk Manager Send Date:	01-Jul-2011	icd
FFS Due Date:			Negotiated Due Date:		
OPP Target Date:					
Fast Track:	<input type="checkbox"/>		New Ingredient:	<input type="checkbox"/>	
Receipt Description:					
Notification to add product logo to label per PR Notice 98-10					
Form A:	<input type="checkbox"/>		Signature Date:		
Form B:	<input type="checkbox"/>		Signature Date:		

Print Letter
 Enter More Information
 Tracking

Receipt Content	Des
Paper Label	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL 28 2011

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Joe Green
Counsel to Copper Development Association
Copper Development Association
260 Madison Avenue
New York, New York 10016

Mail to: Joe Green
Kelley Drye & Warren LLP
Washington Harbour, Suite 400
3050 K Street, NW,
Washington, DC 20007-5108

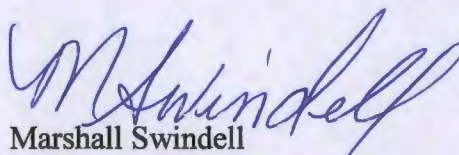
Subject: Antimicrobial Copper Alloys Group III
EPA Registration Number 82012-3
Your Notification Dated June 28th, 2011
EPA Received Date July 1st, 2011

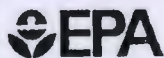
The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add a logo to the product labeling, is acceptable.

The notification has been made part of the registration file.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,


Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82012-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Antimicrobial Copper Alloys Group III	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Copper Development Association Inc. 260 Madison Avenue New York, NY 10016 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) This notification is to add a trademark logo to the label per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. (Please see attached continuation).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>None</u>		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container NA no container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Attached to Bill of Lading			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Joseph J. Green		Title Counsel to CDA		Telephone No. (Include Area Code) 202-342-8849	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Counsel to CDA			
4. Typed Name Joseph J. Green		5. Date June 28, 2011			

EPA APPLICATION FOR PESTICIDE (Section II Cont'd)

I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement, action and penalties under sections 12 and 14 of FIFRA.

7
3
3
3
3

KELLEY DRYE & WARREN LLP

A LIMITED LIABILITY PARTNERSHIP

WASHINGTON HARBOUR, SUITE 400

3050 K STREET, NW

WASHINGTON, D.C. 20007-5108

(202) 342-8400

NEW YORK, NY

CHICAGO, IL

STAMFORD, CT

PARSIPPANY, NJ

BRUSSELS, BELGIUM

AFFILIATE OFFICES

MUMBAI, INDIA

FACSIMILE

(202) 342-8451

www.kelleydrye.com

JOSEPH J. GREEN

DIRECT LINE: (202) 342-8849

EMAIL: jgreen@kelleydrye.com

July 1, 2011

VIA HAND DELIVERY

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202-4501

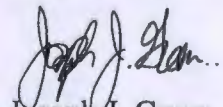
**Re: Antimicrobial Copper Alloys Groups I-VI
EPA Registration Nos. 82012-1, 82012-2, 82012-3, 82012-4, 82012-5,
and 82012-6
Notification to Add Product Logo to Label Per PR Notice 98-10**

Dear EPA:

On behalf of the Copper Development Association ("CDA"), please find the enclosed notifications to add the trademarked "Cu⁺" logo to the approved labels for Antimicrobial Copper Alloys Groups I-VI (EPA Registration Nos. 82012-1 through -6) per Pesticide Registration Notice 98-10. Enclosed is a cover letter explaining the notifications, as well as individual copies of Form 8570-1 and amended labeling for each of the six Antimicrobial Copper Alloy products.

If you have any questions, please contact me at 202.342.8849 or JGreen@KelleyDrye.com.

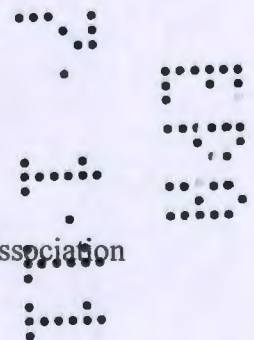
Respectfully submitted,



Joseph J. Green

Counsel to the Copper Development Association

Enclosures



KELLEY DRYE & WARREN LLP

A LIMITED LIABILITY PARTNERSHIP

WASHINGTON HARBOUR, SUITE 400

3050 K STREET, NW

WASHINGTON, D.C. 20007-5108

(202) 342-8400

FACSIMILE

(202) 342-8451

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JOSEPH J. GREEN

DIRECT LINE: (202) 342-8849

EMAIL: jgreen@kelleydrye.com

NEW YORK, NY

CHICAGO, IL

STAMFORD, CT

PARSIPPANY, NJ

BRUSSELS, BELGIUM

AFFILIATE OFFICES

MUMBAI, INDIA

July 1, 2011

Marshall Swindell, Team 33
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: Antimicrobial Copper Alloys Groups I-VI
EPA Registration Nos. 82012-1 through 82012-6
Notification to Add Product Logo to Label Per PR Notice 98-10

Dear Mr. Swindell:

On behalf of the Copper Development Association ("CDA"), enclosed please find notifications to add the trademarked "Cu⁺" logo to the approved labels for Antimicrobial Copper Alloys Groups I-VI (EPA Registration Nos. 82012-1 through -6). Enclosed are individual copies of Form 8570-1 and amended labeling for each of the six Antimicrobial Copper Alloy products. The logo is added as an optional attachment on each label.

The notification is consistent with the requirements of Pesticide Registration Notice 98-10, Section II.N, which provides for label changes that are not misleading (and are otherwise consistent with 40 C.F.R. Part 156) and "involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use." Addition of the "Cu⁺" logo does not involve changes to any of these labeling provisions or, most importantly, alter any claims made for the product. "Cu⁺" is a graphic representation of the copper ion that is the active ingredient in Antimicrobial Copper Alloys and a global trademark used to market the copper brand.

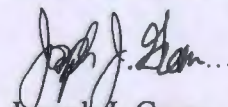
CDA and antimicrobial copper alloy product manufacturers will have the option to utilize the "Cu⁺" logo to indicate that their products are made from [EPA-registered

Antimicrobial Copper Alloys that have been manufactured consistent with ASTM product specifications, as required by the EPA registrations.

Consistent with the registration requirements for Antimicrobial Copper Alloys, labeling and marketing materials, whether they bear the "Cu⁺" logo or not, are required to include specific claims language, including a statement that the use of copper alloys is a supplemental, not a substitute for, standard infection control practices. As demonstrated since obtaining the original registrations in February 2008, CDA and its member companies are committed to proper stewardship of Antimicrobial Copper Alloys.

If you have any questions, please contact me at 202.342.8849 or JGreen@KelleyDrye.com.

Respectfully submitted,



Joseph J. Green

Counsel to the Copper Development Association

Enclosures

ANTIMICROBIAL COPPER ALLOYS - GROUP III AND ASSOCIATED FABRICATED PRODUCTS MASTER LABEL

The Master Label consists of the label that will accompany the Antimicrobial Alloys and a label that will accompany each product fabricated using a registered alloy from Antimicrobial Copper Alloys - Group III.

[Alloy Label – Front Panel]

ANTIMICROBIAL COPPER ALLOYS - GROUP III AND ASSOCIATED FABRICATED PRODUCTS

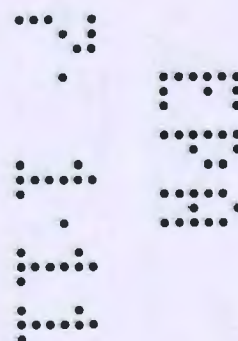
Active Ingredient:

Copper	82.6%
Other	17.4%
Total	100%

EPA Registration No. 82012-3
EPA Establishment No. *****

Made in the United States by *****
Distributed by *****

Net Weight: XXX lbs XXX ounces of [brand name]



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Antimicrobial Copper Alloys - Group III

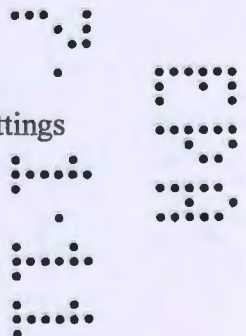
These alloys are only intended for the manufacture and fabrication of touch surface components for use in hospitals, healthcare facilities, and various public, commercial, and residential buildings. [The claims listed on the attached fabricated product label may be made in connection with the marketing and sale of Antimicrobial Copper Alloys - Group III and fabricated products made from Antimicrobial Copper Alloys - Group III under EPA Registration Number 82012-3.]

A list of components that may be fabricated out of Antimicrobial Copper Alloys - Group III is specified below. Antimicrobial Copper Alloys - Group III are not approved for direct food contact or food packaging uses.

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
 - Hospital carts (table surfaces, handles, legs)
 - Computer carts
 - Record carts
 - Phlebotomy carts
 - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Water fountains: bubbler head, drain strainer, handle
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars



- Showerheads
- Countertops and tabletops (non-food use only)
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Instrument handles

Medical equipment knobs, pulls and handles for:

- Drug delivery systems
- Monitoring systems
- Hospital beds
- Office equipment
- Operating room equipment
- Stands and fixtures

Types of knobs: *e.g.*, Prong, fluted, knurled, push/pull, T-handle, tapered, and ball knobs

- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles



- Critical care cart: Table top, drawer, drawer pull, lock, copper wire baskets for storage of equipment and charts.
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Medical records: Chart holders, clipboards, filing systems
- Storage Shelving: wire shelving etc. for medical supplies
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television controls: knobs, buttons, remote
- Monitor (television, computer, etc.) housing
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Pens
- Badge clips
- Name tags
- Patient gown snaps
- Window sills, pulls and locks
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

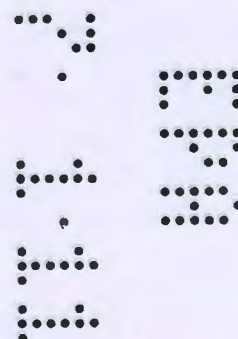
- Shopping cart handles, child seats, handrails
- Cash registers: housing, keypads
- ATM machines: keys, housing
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)
- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Light switches, switch plates



- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Bracelets
- Badge clips
- Name tags
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates
- Clip boards
- Office supplies: paper clips, staplers, tape dispensers

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Showerheads
- Countertops and tabletops
- Hinges, locks, latches, and trim
- Door stops, door pulls, and protector guards
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Thermostat covers, control knobs and wheels
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Ceiling tiles (non-porous)
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Windows (crank), Locking mechanism, pull handles
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Jalousie Windows (crank)



- Casement (cranks, levers, hinges)
- Single and double-hung windows (locks and pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Bedside pitchers
- Closet rods and hangers
- Television remote
- Cup Holder
- Toothbrush holder
- Soap holder
- Magazine rack
- Coat rack and hooks
- Shower curtain rings
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Office supplies: paper clips, staplers, tape dispensers
- Monitor (television, computer, etc.) housing

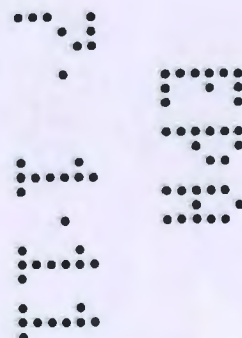
Mass Transit Facilities

- Handrails
- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews
- Eye glass frames and protective eye wear
- Pens
- Combs
- Ashtrays

Do not wax, paint, lacquer, varnish, or otherwise coat touch surfaces.



Antimicrobial Copper Alloys - Group III – Fabricated Products

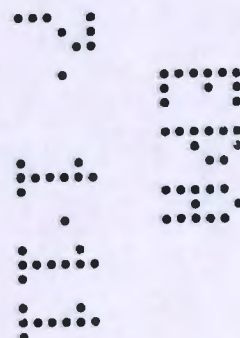
The Antimicrobial Copper Alloys - Group III fabricated products listed above may be sold and distributed under EPA Registration Number 82012-3. Products fabricated with Antimicrobial Copper Alloys - Group III must bear the EPA approved fabricated product label, below, with one or more of the listed claims.

STORAGE AND DISPOSAL

Dispose of excess by recycling.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.



ANTIMICROBIAL COPPER ALLOYS - GROUP III

Fabricated Product Label

FRONT

[This (touch surface) (product)] made from

Antimicrobial Copper Alloys - Group III

Active Ingredient:

Copper 82.6%

Other..... 17.4%

[Total 100.0%]

See [Back/Side Panel][Insert] for Directions for Use

Net Weight: XXX lbs XXX ounces of [brand name]

BACK

ANTIMICROBIAL COPPER ALLOYS - GROUP III

Laboratory testing has shown that when cleaned regularly this surface:

- Continuously reduces bacteria* contamination, achieving 99.9% reduction within 2 hours of exposure.
 - Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
 - Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
 - Kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contaminations.
 - Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.
 - [This product/component name] is made (out of)(from) a (copper)(touch) surface that continuously kills bacteria left behind [by dirty hands][on the surface] killing more than 99.9% of bacteria within 2 hours.
- * *Staphylococcus aureus*, *Enterobacter aerogenes*, Methicillin-Resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* O157:H7, *Pseudomonas aeruginosa* and, Vancomycin - Resistant *Enterococcus faecalis* (VRE).

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. Clean and sanitize according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

Not approved for direct food contact or food packaging uses.

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 82012-3

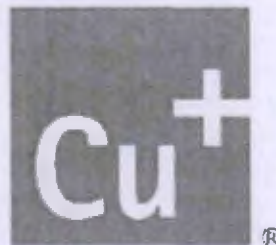
EPA Est. No. [Product Manufacturer Number] 82012-NY-001

Manufactured by: [Product Manufacturer Company Name and Address]

Copper Development Association, 260 Madison Ave., NY, NY 10016-240

[Optional Logo for Use with Alloy Label or Fabricated Product Label]

Antimicrobial
Copper



Changes to label per
PR Notice 98-10

